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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,933	09/20/2001	Luba Cohen	2786-0191P	9933

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EXAMINER
WARE, DEBORAH K

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/955,933	COHEN, LUBA	
	Examiner	Art Unit	
	Deborah K. Ware	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *14 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☒ Claim(s) *1-10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-10 are presented for examination on the merits.

Priority

Foreign priority is acknowledged and the certified document has been received in the instant case.

Information Disclosure Statement

The Information Disclosure Statement (IDS) has been received and entered. The reference(s) submitted therewith have been considered as indicated on the enclosed PTO-1449 Form.

Claim Objections

Claims 1-10 are objected to because of the following informalities: use of abbreviation in the claims wherein the abbreviations are not well defined first in the specification are not suggested. Applicant should either first define them in each of the independent claims or define them at their first usage in the specication for their use in the claims. Also claim 8 has a typo at line 4, "tsimultaneously". Further, the term "trygliceride" may be misspelled since it is believed by the examiner to be spelled as triglycerides. t is suggested that Applicants check all the claims for any other possible misspellings the the examiner may not have noticed.

Claim Rejections - 35 USC § 112

Claims 1-10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-10 fail to set forth proper Markush type language such as –selected from the group consisting of--. It is suggested to use this format because it is uncertain that Applicants' claimed methods require identifying a patient which suffers from all of the listed diseases or health problems/conditions in order for treatment to be successful or whether Applicants intend only one, or whether they intend more than one or more than two or what? The metes and bounds of the claims can not be determined.

Claim 8 is further rendered vague and indefinite for the recitation of the phrase "significantly" because the term can be subjective in its intended meaning. It is suggested to delete the term "significantly" unless Applicants have specifically defined its intended meaning in the specification. Also the step of "by identifying that said patient suffers from high blood tryglicerides and high LDL levels" is unclear with respect to how the step makes its transition to the next step of "simulataneously lowering blood tryglicerides and LDL levels". It is uncertain how these steps are being carried out. The claim fails to set forth clear and distinct process steps for carrying out the method for treating a patient.

Claim Rejection - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kosbab (A).

Claims are drawn to methods for lowering a risk factor in a patient by administering a preparation comprising a licorice extract which is water-insoluble and free from glycyrrhinzinic acid.

Kosbab teaches methods for lowering a risk factor in a patient by administering a preparation comprising a licorice extract which is water-insoluble. See the abstract and col. 23, line 35. Also note col. 11, lines 1-10 wherein it is disclosed that combinations of the preparation include water-insoluble or hydrophobic (having an affinity for lipids). The preparation of Kosbab appears to be free of glycyrrhinzinic acid, with respect to a preparation comprising licorice extract. The risk factor includes blood pressure, glucose concentration, LDL susceptibilities which are attributable to cardiovascular disease and diabetes, note the abstract.

The claims appear to be identical to the disclosure of Kosbab and are therefore, considered to be anticipated by the teachings of the reference. However, in the alternative that there is some slight difference which would render the reference different from the instant claims, the difference is considered to be so slight as to render the claims prima facie obvious over Kosbab. In this alternative, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide for a preparation comprising licorice extract for use in method of lowering risk factors associated with heart disease and diabetes as disclosed by Kosbab. Clearly risk factors, such as blood total cholesterol and LDL levels, blood glucose, blood pressure, etc. are associated diseases with those disclosed by Kosbab.

Thus, even though the reference may not specifically teach each and every disease recited in the instant claims, all of these claimed diseases are at least suggested by Kosbab. A preparation comprising licorice extract would have been expected to provide successful results. Further, the reference is silent of a preparation

free from glycyrrhizinic acid, thus, this suggests that the cited preparation is free from glycyrrhizinic acid too. Therefore, the claims are at least prima facie obvious. However, the instant claims are so close and similar to the teachings of Kosbab that they are at this time considered to be alternatively anticipated by the teachings as indicated above, but if the instant claims are shown to be different somehow, the claims are rendered alternatively prima facie obvious.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 308-4245. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 305-3592 for regular communications and 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0196.

DEBORAH K. WARE
PATENT EXAMINER

Deborah K. Ware
December 16, 2002